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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,238	01/23/2004	Liam Seery	8912/2012	8045

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EXAMINER	
DESAI, ANAND U	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 12/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/764,238	SEERY ET AL.	
	Examiner	Art Unit	
	Anand U Desai, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 23 January 2004.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-67 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-67 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2-11, drawn to a method of identifying an inhibitor of an apoptosis-associated protein that is encoded by a gene selected from Table 1B, classified in class 435, subclass 7.9.

II. Claim 12, and 16, drawn to a method of identifying an activator of apoptosis, classified in class 530, subclass 350.

III. Claims 13-15, and 17-20, drawn to a method of identifying an inhibitor of tumor growth, classified in class 435, subclass 7.1.

IV. Claims 21, and 22, drawn to an inhibitor of tumor growth, classified in class 514, subclass 131.

V. Claims 23-28, drawn to a method of inhibiting tumor growth in mammal in recognized need of such treatment, classified in class 435, subclass 91.3.

VI. Claims 29, and 30, drawn to a method of preparing a composition comprising a chemical compound which specifically binds to and inhibits an apoptosis-associated protein, classified in class 424, subclass 489.

VII. Claims 31, 32, and 38, drawn to a method for identifying neoplasias responsive to treatment with compounds that selectively inhibit neoplasia, classified in class 424, subclass 9.2.

VIII. Claim 34, drawn to a method for identifying neoplasias responsive to treatment with an inhibitor, comprising determining the amount of the protein in the neoplastic tissue sample, classified in class 530, subclass 387.9.

IX. Claim 35, drawn to a method for identifying neoplasias responsive to treatment with an inhibitor, comprising determining the amount of mRNA in the neoplastic tissue sample, classified in class 530, subclass 388.21.

X. Claim 36, drawn to a method for identifying neoplasias responsive to treatment with an inhibitor, comprising determining the amount biochemical activity of the protein in the neoplastic tissue sample, classified in class 424, subclass 9.6.

XI. Claim 37, drawn to a method for identifying neoplasias from a patient responsive to treatment with an inhibitor of an apoptosis-associated protein, comprising contacting the sample with an antibody, classified in class 530, subclass 387.1.

XII. Claims 39, drawn to a method of detecting the presence in a sample of an apoptosis-associated polypeptide, comprising hybridizing at least a 15 nucleotide sequence with a sample containing DNA or RNA, classified in class 435, subclass 6.

XIII. Claim 40, drawn to a method of detecting the presence in a sample of an apoptosis-associated polypeptide, comprising incubating a biological sample with an antibody capable of binding to the apoptosis-associated polypeptide, classified in class 530, subclass 387.2.

XIV. Claims 41, 42, 45, 46, and 48, drawn to a method of modulating apoptosis in a cell, the method comprising transforming into the cell a double-stranded nucleic acid sequence encoding a polypeptide, classified in class 536, subclass 23.1.

XV. Claims 43, 47, and 49, drawn to a method of modulating apoptosis in a cell, the method comprising transforming into the cell a double-stranded nucleic acid sequence having at least 80% sequence identity with a nucleic acid sequence encoding a polypeptide, classified in class 536, subclass 23.1.

XVI. Claim 44, drawn to a method of modulating apoptosis in a cell, the method comprising transforming into a cell an isolated nucleic acid molecule comprising a regulatory sequence linked to a nucleic acid sequence that encodes a ribonucleic acid precursor, wherein the precursor comprises a stem and loop structure, classified in class 536, subclass 23.1.

XVII. Claims 50, and 51, drawn to an isolated RNA, classified in class 536, subclass 23.1.

XVIII. Claim 52, drawn to a host cell transformed with nucleic acid molecule comprising a double-stranded nucleic acid sequence linked to a regulatory sequence, classified in class 435, subclass 69.1.

XIX. Claim 53, drawn to a method of providing a mammal with an anti-proliferative protein, comprising introducing into the mammal a mammalian cell transformed with a nucleic acid molecule, classified in class 424, subclass 93.2.

XX. Claims 54, and 55, drawn to a method for treating a disease or condition characterized by abnormal apoptosis in mammalian tissue, the method comprising contacting the tissue with a RNA precursor, classified in class 514, subclass 44.

XXI. Claim 56, drawn to a pharmaceutical composition comprising, as an active ingredient, an apoptosis associated nucleic acid, and a pharmaceutically-acceptable carrier, classified in class 424, subclass 493.

XXII. Claim 57, drawn to a pharmaceutical composition comprising an apoptosis-associated polypeptide, and a pharmaceutically-acceptable carrier, classified in class 424, subclass 491.

XXIII. Claim 58, drawn to a pharmaceutical composition comprising as an active ingredient, an antibody to an apoptosis-associated nucleic acid, and a pharmaceutically-acceptable carrier, classified in class 530, subclass 387.1.

XXIV. Claim 59, drawn to a pharmaceutical composition comprising, as an active ingredient, an antibody to an apoptosis-associated polypeptide, and a pharmaceutically-acceptable carrier, classified in class 530, subclass 387.1.

XXV. Claim 60, drawn to a method for diagnosing a disease or condition characterized by abnormal apoptosis in mammalian tissue, the method comprising contacting the tissue with an antibody, and detecting an antibody/antigen complex, classified in class 435, subclass 7.1.

XXVI. Claim 61, drawn to a method for treating a disease or condition characterized by abnormal apoptosis in mammalian tissue, the method comprising contacting the

tissue with an antagonist of an apoptosis-associated polypeptide having a sequence as set out in Table 1B, classified in class 435, subclass 334, and 339.

XXVII. Claim 62, drawn to a method for treating a disease or condition characterized by abnormal apoptosis in mammalian tissue, the method comprising contacting the tissue with an agonist of an apoptosis-associated polypeptide having a sequence as set out in Table 1B, classified in class 435, subclass 334, and 339.

XXVIII. Claim 63, drawn to a kit for treating a disease or condition characterized by abnormal apoptosis in mammalian tissue, the kit comprising a polypeptide encoded by a nucleic acid, a nucleic acid, or an antibody, classified in class 536, subclass 23.1, class 530, subclass 350, and 387.1.

XXIX. Claim 65, drawn to an array comprising at least two apoptosis genes, wherein the nucleic acid sequences are DNA seqeunces, classified in class 536, subclass 24.3.

XXX. Claim 66, drawn to an array comprising at least two apoptosis genes, wherein the nucleic acid sequences are RNA seqeunces, classified in class 536, subclass 24.3.

XXXI. Claim 67, drawn to an array comprising at least two apoptosis proteins, classified in class 530, subclass 402.

2. Claim 1 link(s) inventions I, II, and III. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable

linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

3. Claim 33 link(s) inventions VIII, IX, and X. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 33. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. Claim 64 link(s) inventions XXIX, XXX, and XXXI. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 64. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant

application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

5. Inventions I-III, V-XVI, XIX, XX, and XXV-XXVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the multiple different method inventions use different materials with different modes of operation, and different effects.

6. Inventions IV, XVII, XVIII, XXI-XXIV, and XXVIII-XXXI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the multiple different composition inventions have different modes of operation, and different effects.

7. Inventions IV and V, VII, XI, XIV-XVI, XIX, XX, XXVI, XXVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (MPEP § 806.05(h)). In the instant case the multiple materially different inhibitors of tumor growth as claimed in invention IV can be used in the materially different processes of inventions V, VII, XI, XIV-XVI, XIX, XX, XXVI, XXVII.

8. Because these inventions are distinct for the reasons given above and the search required for the inventions is not coextensive, restriction for examination purposes as indicated is proper. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction

requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

December 23, 2004

JON WEBER
SUPERVISORY PATENT EXAMINER